

## **REMARKS**

Claims 1-15, 26-29, 31-40 are pending in this application. Claims 27-29 have been withdrawn. Claims 1-25, and 30 have been cancelled. Claims 31-40 have been previously presented. Claims 41-44 are new. No claims are currently amended. Claims 26, and 27 are independent claims.

## **Amendments to the Specification**

Applicant has amended ¶¶ [0001] and [0009] and respectfully requests those paragraphs to be replaced with the paragraphs above. No new subject matter has been added.

## **35 U.S.C. § 112, ¶ 1 Rejection**

### **Claim 31**

The Office has rejected claim 31 as failing to comply with the enablement requirement of 35 U.S.C. § 112, ¶ 1. Applicant has attached a declaration signed by the Applicant pursuant to the Office's suggestion in the Office Action mailed June 25, 2009, which at least states the deposit meets all of the criteria set forth in 37 C.F.R. §§ 1.901-1.809. Further, the deposit is referred to in the body of the specification at least at ¶ [0009] and is identified by accession number, date of deposit, name and address of the depository and the complete taxonomic description. As Applicant has complied with all deposit requirements, Applicant respectfully requests the Office withdraw this rejection of claim 31.

### 35 U.S.C § 101 Rejection

#### Claim 26 and 38-40

The Office has rejected claims 26 and 38-40 as being directed to non-statutory subject matter under 35 U.S.C. § 101. The claims require "a pharmacologically active dose of a bacterium of the genus *Dietzia*, an active fragment thereof, a protein secreted therefrom, or combinations thereof". The Office states that Duckworth et al. teaches a strain of a *Dietzia* found in a natural soda lake and goes on to state the "claims do not recite the composition to be isolated or in some way separate from the natural environment." The Office has erred in its analysis. Applicant respectfully traverses the rejection.

The Office incorrectly characterizes the disclosure of Duckworth et al. In its abstract Duckworth et al. states "[t]wo novel alkaliphilic aerobic organotrophic bacteria have been isolated from a moderately saline and alkaline East African soda lake. The new isolates...are members of the monospecific genus *Dietzia*" (emphasis added). Contrary to the Office's position, Duckworth et al. does not disclose that bacterium of the genus *Dietzia* are found in nature, but rather the reference discloses that such bacterium is "isolated" from East African soda lakes (i.e., nature) and are thus, "isolated or in some way separate from the natural environment", as the Office requires in ¶ 7 of the Office Action dated June 25, 2009. Therefore, the claimed bacterium does not read on a product of nature and Applicant respectfully requests the Office withdraw the rejection.

Further, the "bacterium of the genus *Dietzia*" recited is required to be a "pharmacologically active dose" and there is no suggestion that such a dose of the

bacterium is found in nature without being “isolated or in some way separate from the natural environment”. There is also no suggestion that the bacterium is naturally found in such quantity or quantities so as to be pharmacologically active. Thus, the Office has failed to satisfy its burden to show that the required pharmacologically active dose of the bacterium of the genus *Dietzia* is naturally occurring. Therefore, the claimed bacterium does not read on a product of nature and Applicant respectfully requests the Office withdraw the rejection.

### **35 U.S.C § 102(b) Rejection of Claims 26 and 38-40 – Nishimaki et al.**

Claims 26 and 38-40 have been rejected under 35 U.S.C. § 102(b) as being anticipated by Nishimaki et al. (5,989,892), as evidenced by Rainey et al. The office states Nishimaki et al. discloses compositions of the bacteria of the species *Rhodococcus maris* and Rainey et al. teaches *Rhodococcus maris* was renamed *Dietzia maris*. The office further notes that “the reference teaches compositions comprising bacteria of the genus *Dietzia*, which would perform the function recited in the claims” (emphasis added). However, the Office provides no support for the proposition. The Office states the standard for meeting an intended use limitation, which is that “[i]f the prior art structure is capable of performing the intended use, then it meets the claim [limitation]”. The Office fails to show that Nishimaki et al. teaches a pharmacologically active dose of the bacterium. It also fails to show that Nishimaki et al. discloses its bacterium is capable of reducing or preventing the symptoms of a disease or syndrome caused by mycobacterium or any other etiologic agent.

Applicant respectfully asserts the Office has erred in its conclusion because there

is absolutely no indication in the references that the compositions of Nishimaki et al. are capable of performing the function recited in claim 26, much less are comprised of a pharmacologically active dose of the bacterium. Any such indication that a pharmacologically active dose of the composition of Nishimaki et al. (which is not shown in the references) may be used to prevent or reduce symptoms of a disease or syndrome must have been gleaned from Applicant's application for patent, which is per se impermissible. See MPEP § 2141.01(III). As it is clear that the cited reference, Nishimaki et al, in view of Rainey et al. fails to teach all features or elements of claim 26, Applicant respectfully requests the Office withdraw this rejection of claim 26 and the claims that depend therefrom (claims 38-40).

### **35 U.S.C § 102(b) Rejection of Claims 26 and 38-40 – Duckworth et al.**

Claims 26 and 38-40 have been rejected under 35 U.S.C. § 102(b) as being anticipated by Duckworth et al. The office states Duckworth et al. discloses a strain of *Dietzia* and compositions comprising the isolated strain. The office further states the strain and compositions thereof "would perform the function recited in the claims" (emphasis added). The Office provides no support or rationale as to why the isolated strains or compositions thereof would perform the function. Moreover, the Office fails to show Duckworth et al. teaches a pharmacologically active dose of the bacterium or that Duckworth et al. discloses its bacterium is capable of reducing or preventing the symptoms of a disease or syndrome.

Applicant respectfully asserts the Office has erred in its conclusion, as there is no indication in the reference that the compositions of Duckworth et al. are capable of

performing the function recited in claim 26, much less are comprised of a pharmacologically active dose of the claimed bacterium. Any such indication that a pharmacologically active dose of the composition of Duckworth et al. (which is not shown in the references) may be used to prevent or reduce symptoms of a disease or syndrome must have been gleaned from Applicant's application for patent, which is per se impermissible. See MPEP § 2141.01(III). As it is clear that the cited reference, Duckworth et al., fails to teach all features of claim 26, Applicant respectfully requests the Office withdraw this rejection of claim 26 and the claims that depend therefrom (claims 38-40).

**35 U.S.C § 103(a) Rejection of Claims 26 and 31-40 – Alkemade et al in view of Mosser and Rainey et al.**

Claims 26 and 31-40 have been rejected as being unpatentable over Alkemade (6,139,844) in view of Mosser (WO 99/05304) and Rainey et al. In making the combination, the Office has made numerous assumptions that are not supported by the references. Therefore, Applicant asserts the references are improperly combined and/or come to an unsupported conclusion and the Office has failed to provide a prima facie case of obviousness. Without conceding arguments regarding the substantive disclosure of the cited references, Applicant traverses the rejection as set forth below.

At ¶ 21, the Office states "Rainey teaches that members of the genus *Dietzia* are closely related to *Rhodococcus* and were once considered to be in the same genus (p. 359)". Yet Rainey et al. teaches away from the characterization the Office asserts. For example, Rainey et al discloses that "*R. maris* cannot be considered an authentic

member of the genus *Rhodococcus*" based on the tests and study discussed in the paper. Rainey et al., P. 32, Col. 1. Although *Dietzia* may belong to the same phylogenetic group as *Rhodococcus* (see p. 35, Col. 1), Rainey et al. goes on to state "[t]he genus *Dietzia* can be readily distinguished from other mycolic acid-containing taxa [e.g., *Rhodococcus*] by the criteria shown in Table 2". Rainey et al. P. 35, Col. 1. Thus, although *Dietzia maris* was formerly classified in the genus *Rhodococcus*, such classification was premature and persons in the art do not consider the *Dietzia* genus closely related to *Rhodococcus* genus. To say that "species of the genus *Dietzia* were known to be closely related to and sometimes synonymous with *Rhodococcus*", (see Pages 8 and 9 of Office Action), is contrary to the explicit teaching of Rainey et al. and contrary to the phylogenetic classification system (i.e., in the classification system, it is not possible to have a species in one genus that is synonymous with a species in another genus).

Further, the Office states "Alkemade and Mosser teach that one would have a reasonable expectation of success in selecting any species of *Rhodococcus* or related organisms for the preparations of compositions such as those recited in the claims". After reviewing the Alkemade and Mosser references, Applicant is unable to find support for such a proposition and the Office offered no such support in its rejection. There is no indication in either reference that any species of *Rhodococcus* or related organisms may successfully lead to the Applicant's claimed compositions. Further, considering Rainey et al. teaches away from such a proposition, as discussed above, there is no indication that a person having ordinary skill in the art would believe there is a reasonable expectation of success in selecting any species of *Rhodococcus* or related

organism for the preparation of the claimed compositions.

The Office also states that it would have been possible “to choose from the finite number of identified, predictable species of bacteria for the preparation” of the compositions in the claims, *Dietzia maris* being one of those compositions. Contrary to the Office’s assertion the references do not disclose a “finite number of identified, predictable species” of bacteria to use in preparation of a composition. After requiring the finding of a recognized problem for an “obvious to try” rationale, MPEP § 2143(E) requires the Office to make “a finding that there had been a finite number of identified, predictable potential solutions to the recognized need or problem”. The Office specifically states “none of the references specifically teach compositions comprising bacteria of the genus *Dietzia*” (Office Action, Page 9); thus, it is clear that the prior art DOES NOT teach each element of the solution as claimed in Claims 26 and 31-40. Thus, there is no showing of a finite number of identified, predictable species for one to choose from to make the claimed composition.

Further, Claim 31 requires a “bacterium [ ] deposited with the American Type Culture Collection as Accession Number PTA-4125”. The Office failed to address this claim limitation. Applicant asserts in its Specification that the deposited bacterium is novel and previously undiscovered. See ¶ [0036], Lines 1-4. Although the Office makes the blanket assertion the solution was identified in the prior art (Office Action, Page 9, Lines 6-9), it fails to particularly point out where in the art the particular solution, claimed as a feature of Claim 31, was present in the prior art at the time of the invention. As this particular species (a claimed solution) is unique and previously undiscovered the Office CANNOT logically assert it would have been obvious to make

the claimed particular composition based on a "finite number of identified, predictable species".

Due to the foregoing, including: 1) an incomplete understanding or improper application of Rainey et al.; 2) a misunderstanding or misapplication of the phylogenetic classification system and what is taught by the classifications; 3) an improper obviousness rationale due to there being no finite number of identified, predictable species, and if there were, the particular species of the genus *Dietzia* was not part of those identified; and 4) not addressing the claim elements of claim 31, there is no prima facie case of obviousness with respect to claims 26 and 31-40. Applicant respectfully requests the Office withdraw the rejection.

#### **Finality of the Next Action Precluded – Obviousness**

Applicant notes the Office has failed to set forth a prima facie case of anticipation or obviousness with respect to claims 26 and 31-40. Thus, due to the points above, the Office has not shown the subject matter of the current claims to be unpatentable. Applicant respectfully submits that this omission amounts to a failure to articulate a prima facie case of unpatentability and the burden to rebut the 35 U.S.C. §§ 102(b) and 103(a) "rejections" and present evidence of claim changes or nonobviousness has not yet shifted to the Applicant. See MPEP § 2142. Consequently, a next Office action rejecting claims 26 or 31-40 cannot properly be made final because only then would the Applicant be obligated to rebut the rejection, presuming that such an Office action sets forth a prima facie case of unpatentability. (See MPEP § 706.07(a)).



### CONCLUSION

Applicant respectfully submits that the application is in condition for review and allowance.

Applicant's undersigned attorney may be reached by telephone at (715) 835-5232 or by facsimile at (715) 835-9890. All correspondence should be directed to the below listed address.

Respectfully Submitted,

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